Amendment Dated: July 13, 2005

# REMARKS

Applicants have now had an opportunity to carefully consider the Examiner's comments set forth in the Office Action of May 18, 2005.

Reconsideration of the Application is requested.

## Interview Summary

In the interview with the Examiner on June 14, 2005, Applicants discussed the language for claims which would be considered allowable. Based on these discussions, Applicants reviewed the pending claims and on July 1, 2005, held further discussions with the Examiner. The Examiner indicated that the language for several of the Applicants' proposals would define over the prior art and overcome the §112 rejections. The present set of pending claims are those which Applicants understand were considered to be allowable. Applicants appreciate the time taken by the Examiner in this regard.

# Status of Application

Claims 219 and 224-257 are pending in the application.

Claims 1-218 and 220-223 are canceled without prejudice.

New claims 224-257 are added.

#### The Office Action

Previous claims 197, 206, 211, 213, 218, 221, and 223 stand withdrawn. Applicants respectfully request rejoinder of new method claims 233, 237, 241, 245, 249, 253 and 257 should an allowable product claim be found.

Claims 184 and 187 were rejected under 35 USC 102(b) as being anticipated by Xuan-II (Xuan, et al., J. Cellular Biochem., 65:172-185, 1997).

Claims 184, 185, 187, 190-196, 198-205, 207,-210, 212, 214-217, 220, and 222 stand rejected under 35 U.S.C. 112, first paragraph.

Claims 186, 188, 189 were objected to for depending on a rejected base claim.

Claim 219 was considered to be allowable.

For the reasons outlined below, it is submitted that claims 219 and 224-257 are now in condition for allowance.

Previous claims 1-183 and 220-223 have been canceled and replaced with new claims 224-257.

### The §112 rejections

Applicants have attended to each of the §112, first paragraph, rejections, through newly presented claims 224-257 and/or through identification of support from the specification. Accordingly, is respectfully requested that the rejections be withdrawn.

### The Claims are in Condition for Allowance

Claim 219 relates to a polypeptide comprising at least two repetitions of the amino acid sequence defined in SEQ ID NO.:5. Claims 230-233 relate to a pharmaceutical composition containing the polypeptide and to a method of treating a patient having prostatic adenocarcinoma, comprising administering the pharmaceutical composition. Claim 219 was considered to distinguish over the prior art. Accordingly it is submitted that claims 230-233 are also allowable.

Claim 224, which is similar to prior claim 185, addresses the §112, first paragraph, rejections raised by the Examiner in the last Office Action. No prior art rejections were raised against this claim. The Examiner, in rejecting claim 185, considered that the specification contemplates sequences derived from SEQ ID NO.:1 which comprise SEQ ID NO: 5. Since SEQ ID NO: 5 has fifteen amino acids, claim 224 now recites a polypeptide of from 15 to 64 contiguous amino acids of SEQ ID NO.: 1 which inhibits the growth of prostatic adenocarcinoma, wherein the polypeptide comprises SEQ ID NO: 5.

Support for new claims 224 and 234-237 is to be found in original claims 2, 55 and 86, and in prior claims 184, 185, 207 and 209, and in sequence IDS 10-88.

The prior art does not disclose such a polypeptide. Xuan-II discloses a polypeptide M23 comprising 22 residues, amino acids 21-42 of PSP 94. This fragment comprises only amino acids 1-12 of SEQ ID No: 5.

Atty. Dkt. No. CLWZ 200147 Application Serial No. 09/977,406 Amendment Dated: July 13, 2005

In the telephone interviews with the Examiner, this claim and dependent claims drawn to a pharmaceutical composition and method of treating a patient having prostatic adenocarcinoma, were considered to be allowable. Accordingly, it is submitted that claim 224 and dependent claims 234-237 are allowable.

Claim 225 is similar to previous claim 186, which was considered to be allowable if placed in independent form. In the Examiner interviews, the Examiner considered that this claim and dependent claims drawn to a pharmaceutical composition and method, would be allowable. Accordingly, it is submitted that claim 224 and dependent claims 238-241 are allowable.

Claim 226 is similar to previous claims 188 and 189, which were considered to be allowable in the last Office Action. Support for new claims 226 and dependent claims 242-245 is to be found in original claims 2, 55, 86 and in prior claims 175, 176, 188, 189, 194, 195. The Examiner considered that prior claims 188 and 189 would be allowable if placed in independent form. Claim 226 now recites the specific polypeptides listed in these claims.

In the Examiner interviews, the Examiner considered that this claim and dependent claims drawn to a pharmaceutical composition and method, would be allowable. Accordingly, it is submitted that claim 226 and dependent claims 242-245 are allowable.

Claims 227, 228, and 229 respectively recite a polypeptide which inhibits the growth of prostatic adenocarcinoma, said polypeptide having at least 50% (or 70% or 90%) of its amino acid sequence identical to the amino acid sequence defined in SEQ ID NO.:5.

Support for claims 227, 228, and 229 and for dependent claims 246-257 is to be found in original claims 2, 55, 86, in prior claims 175, 176, 199, 203, and 204, and, for example, in SEQ ID. NO. 24. Prior claim 199 was considered to define over the prior art. The Examiner considered that the specification was not enabling for treatment of polypeptides that inhibit any type of tumor cell. While applicants do not concede that the specification lacks enablement, claims 227, 228, and 229 now recite that the polypeptide is one which inhibits the growth of prostatic adenocarcinoma and makes no specific claim to tumor cells in general. Claim 227 encompasses a polypeptide which includes SEQ ID NO.:5 and which may be up to

Atty. Dkt. No. CLWZ 200147

Application Serial No. 09/977,406

Amendment Dated: July 13, 2005

30 amino acids in length, such as SEQ ID NOS.: 5, and 10-24. In the telephone interviews, the Examiner agreed that these claims, and dependent claims 246-257 would be allowable. Accordingly, it is submitted that claims 227, 228, and 229 and dependent claims 246-257 are allowable.

Accordingly, it is submitted that claims 246-257 are in condition for allowance.

In view of the Examiner's restriction requirement, the Applicant retains the right to present the non-elected claims with respect to SEQ ID NO.: 2, 3, 4, 6, 7 and SEQ ID NO.: 2, 3, 4, 6, 7 analogs in a divisional application.

## CONCLUSION

For the reasons detailed above, it is submitted claims 219 and 224-257 are now in condition for allowance. An early allowance of these claims is respectfully requested.

In the event the Examiner considers further personal contact advantageous to the disposition of this case, she is hereby authorized to call Ann M. Skerry, at telephone number (216) 861-5582.

Respectfully submitted,

FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP

July 13, 2005

Ann M. Skerry

Reg. No. 45,655

1100 Superior Avenue, 7<sup>th</sup> Floor Cleveland, Ohio 44114-2579

Telephone: (216) 861-5582

L:\AMS\2005\JUL\ciwz200147 fianal.doc